



UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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IN RE: ZIMMER M/L TAPER HIP :
PROSTHESIS OR M/L TAPER :
HIP PROSTHESIS WITH KINECTIV :
TECHNOLOGY AND :
VERSYS FEMORAL HEAD PRODUCTS :
LIABILITY LITIGATION :
:

MDL NO. 2859

18-MD-2859 (PAC)

18-MC-2859 (PAC)

ORDER NO. 13

This Document Relates to All Cases
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PATHOLOGY AND MEDICAL DEVICE PRESERVATION PROTOCOL

I. Scope of Order

Discovery in this proceeding may involve the collection, storage, preservation, and production of pathology specimens and/or retrieved or explanted medical devices, evidence for which special handling, storage, and preservation procedures may be warranted. Therefore, the Court enters this stipulated pathology and medical device preservation protocol order ("Pathology and Medical Device Preservation Protocol Order" or "Order") in the matters consolidated in MDL 2859, which will in turn govern state court matters coordinated with MDL 2859 (the "Litigation").

II. The Order

It is hereby **ORDERED** as follows:

A. Definitions

"Explanted Product" is defined as any hip replacement component extracted from a plaintiff in a revision surgery involving findings or suspicion of corrosion, adverse local tissue reaction, metallosis, ALVAL, elevated metal ion levels in the blood or joint, necrosis, pseudotumor, and similar complications.¹

¹ For any "Explanted Product" that is not the subject of Plaintiffs' claims in this litigation, a competing preservation order or request arising from a litigation or regulatory action that directly relates to the Explanted Product shall take

“Material” or “Materials” is defined as any Explanted Products or any portion thereof retrieved, explanted, or excised from a Plaintiff, and gross and microscopic specimens, which may contain portions of an Explanted Product, pathology evidence, histology slides, paraffin blocks, and/or stock jars containing tissue, synovial fluid, blood serum, gross material, and/or an Explanted Product.

“Destructive Testing” is defined as any testing or inspection methods that in any way alter the structure, existence, integrity, appearance, or nature of the Materials—including their surfaces—from their explanted condition.

“Facility” is defined to include healthcare facilities where a plaintiff underwent a surgery or procedure involving extraction of Materials, and facilities responsible for the preservation and/or maintenance of retrieved, explanted, or excised Materials.

“Non-Destructive Testing” is defined as any testing or inspection methods that will not alter the structure, existence, integrity, appearance, or nature of the Materials—including their surfaces—from their explanted condition.

“Plaintiff” means an individual with a filed lawsuit pending before this Court as part of MDL 2859.

“Zimmer Defendants’ Counsel” means a single lawyer, at a single address, that the Zimmer Defendants so designate to receive notice of Plaintiff’s preservation efforts consistent with this Order.

B. Intent

It is the intention of the Parties that all Materials be preserved in a manner that permits the Parties equal access to and analysis of the Materials, and that neither Party will alter the Materials

precedence over this Order and a failure to preserve shall not constitute spoliation so long as Plaintiffs provide notice and supporting documents to the Zimmer Defendants.

in any way prior to reaching an agreement in writing regarding the testing or inspection of the Materials. Only if no such agreement can be reached will the Parties seek the Court's guidance.

C. Protocol for Preservation of Materials from Future Procedures

Upon receiving information that a Plaintiff with a filed lawsuit within the scope of the Litigation has scheduled a procedure involving extraction of Materials, Plaintiff's Counsel shall send a letter, with a copy to the Zimmer Defendants' Counsel, to the Facility where the revision or explant surgery is to occur in the form attached hereto as Attachment A, or in a form that is substantially similar such that it is sufficient to advise the Facility of the need to collect, preserve, and document the Material as potential evidence in the Litigation. Plaintiff's Counsel shall also include with the letter a Chain of Custody form in the form attached hereto as Attachment B, or in a form substantially similar such that it provides sufficient information to track the transfer of custody of the Materials, which the Parties shall request that the Facility execute for any Material leaving the possession of the Facility. Additionally, Plaintiff's Counsel shall provide to the Facility a HIPAA-compliant authorization and any other form requiring a Plaintiff's signature for the collection of the Material.

After the letter has been sent to a Facility, Plaintiff's Counsel will pay any costs or fees associated with the preservation and shipment of Materials to Plaintiff's Counsel's office or an appropriate third-party medical evidence storage provider of Plaintiff's choice.

D. Protocol for Identification and Handing of Materials Currently Available at a Facility

Unless Plaintiff's Counsel has already done so, within thirty (30) days of entry of this Order, Plaintiff's Counsel shall send a letter, with a copy to the Zimmer Defendants' Counsel, to any Facility at which Plaintiff's Counsel knows a Plaintiff in this Litigation underwent a procedure that potentially involved extraction of Materials, to determine whether the Facility maintains

possession of Materials. The letter shall be in the form attached hereto as Attachment C, or in a form that is substantially similar such that it is sufficient to advise the Facility of the need to preserve the Material as potential evidence in the Litigation. Plaintiff's Counsel shall also include with the letter a Chain of Custody form in the form attached hereto as Attachment B, or in a form substantially similar such that it provides sufficient information to track the transfer of custody of the Materials, which the Parties shall request that the Facility execute for any Material leaving the possession of the Facility. Additionally, Plaintiff's Counsel shall provide to the Facility a HIPAA-compliant authorization and any other form requiring a Plaintiff's signature for the collection of the Material.

After a letter in the form set forth in Attachment C has been sent to a Facility, Plaintiff's Counsel will pay any costs or fees associated with the preservation and shipment of Materials from the Facility to Plaintiff's Counsel's office or a third-party medical evidence storage provider.

E. Protocol for Handling of Currently Available Materials Existing in Possession or Control of the Parties, and Future Obtained Materials

1. Notice of Available Material

If Plaintiffs are already in possession of any Materials as of the date of this Order, that information should be noted in the Plaintiff Preliminary Disclosure, governed by separate order.

Similarly, if the Zimmer Defendants are already in possession of any Materials as of the date of this Order, the Zimmer Defendants shall notify Plaintiffs' Counsel in writing of the existence of the Materials and the present location of the Materials in the Defendant Fact Sheet.

2. Preservation of Materials

The Parties agree to utilize reasonable efforts to safeguard the Materials by utilizing appropriate methods in all aspects of shipping, handling, inspection, and testing to avoid alteration of the Materials in any manner not agreed to herein. To the extent possible, Materials should be

handled one at a time at each stage of the handling process to prevent errors in identifying, handling, labeling, or packaging Materials. Standard precautions for handling biological materials should be used when handling Materials and their inner-most packaging. Recognizing that each explant procedure is within the purview and control of non-party medical practitioners and hospitals, any departure from this Order by non-party practitioners and hospitals shall not constitute spoliation of evidence by any of the Parties. Likewise, reasonable compliance with this Order, or with another retrieval analysis protocol that is non-destructive and consistent with the methods and practices accepted by those in the field of inspection and testing of orthopedic devices, and with this Order, shall not constitute spoliation of evidence. The Parties will not object to retrieval and analysis of Materials that is either reasonably consistent with this Order or another retrieval analysis protocol that is non-destructive and consistent with methods and practices accepted by those in the field of the inspection and testing of orthopedic devices and with this Order.

The Parties agree that no Destructive Testing of any Materials shall be undertaken by any Party until each Party and their selected consultants (whether testifying or non-testifying) have had a full and fair opportunity to independently inspect the Materials. Any Party who wishes to undertake Destructive Testing of any kind must provide thirty (30) days advance written notice to all counsel of record for the Plaintiff whose Materials are at issue and to the Zimmer Defendants' Counsel. The Party proposing the Destructive Testing will describe the nature, purpose, and methodology of the proposed testing, as well as identify the individuals who will be conducting the testing and the location, date, and time for the testing. The opposing Party has a right to object to the proposed Destructive Testing in whole or in part, including but not limited to an objection to the timing of the Destructive Testing. If the Parties cannot agree on the proposed Destructive

Testing, then the Parties agree to suspend any Destructive Testing until an agreement can be reached in writing or the issue can be addressed by the Court. If the Destructive Testing proceeds, then the opposing Party has a right to attend in person with representatives and/or consultants of the opposing Party's selection, and to videotape the testing. If the Destructive Testing proceeds, then the Parties shall both have a full and fair opportunity to independently examine the Materials in their altered state. No Materials shall be disposed of—by Destructive Testing or otherwise—absent a separate written agreement by the Parties or a Court order.

3. Shipment of Materials

Upon request by the opposing Party, any Party in possession of Materials will document the Materials on a Chain of Custody form in the form attached hereto as Attachment B, or in a form substantially similar such that it provides sufficient information to track the transfer of custody of the Materials, and ship the Materials to the address of the opposing Party's choosing for its own analysis. All costs and fees associated with the shipment of the Materials under this protocol shall be borne by the Party initially in the possession of the Materials. Should the Party initially in possession of the Materials request the return of the Materials, the Party who requested the Materials shall bear the costs and fees of returning them.

The Parties will follow the following protocol for the shipment and inspection of the Materials:

- a. Photograph all sides of the Materials with a high-resolution camera before packaging and shipping;
- b. Package the Materials so that all surfaces are protected;
- c. Send the Materials via a third-party carrier providing a traceable record;

- d. Upon receipt of the Materials, the receiving Party or its consultant/designee will photograph all sides of the Materials with a high-resolution camera and document receipt of the Materials on the Chain of Custody Form;
- e. No Destructive Testing affecting the condition of the Materials will occur;
- f. Non-Destructive Testing and inspection of the Materials may occur pursuant to the terms and conditions set forth above;
- g. Upon returning or shipping the Materials to additional Parties (e.g., experts or consultants) for inspection, the shipping and receiving Parties will follow the same requirements in section a—f above.

G. No Waiver

Nothing herein shall be construed to preclude a Party from challenging the method of preservation of any Materials.

The Court DIRECTS the Clerk to file a copy of this order in MDL 2859, and it shall apply to all cases that are or become a part of MDL 2859 or are coordinated with MDL 2859.

APPROVED the 7th day of March, 2019.



Hon. Paul A. Crotty
Judge of the United States District Court
Southern District of New York

ATTACHMENT A

**VERY IMPORTANT—REQUEST FOR PRESERVATION OF PATHOLOGY
MATERIALS AND/OR MEDICAL DEVICES FROM UPCOMING PROCEDURE**

[Date]

Attn: Departments of Surgery and Pathology
[Address of Retrieval/Explant Facility]

Re: [Case Caption]

Dear Departments of Surgery and Pathology:

I represent the Plaintiff, [Plaintiff's name], and the attorneys copied below represent the Zimmer Defendants in the above-referenced lawsuit. There is no litigation pending against your facility or the treating physician in this matter. I write to request the preservation of blood serum, pathology materials, and/or medical devices ("Materials") from [Plaintiff's name]'s upcoming procedure, scheduled for [date] to be performed by Dr. [Retrieval/Explant Physician].

It is very important that any pathology and/or medical devices obtained during this upcoming procedure be preserved for future analysis by the parties' respective experts. The parties request that you preserve the Material(s) obtained as follows:

Instructions for Immediate Preservation of the Material(s):

1. Please preserve **all** retrieved or explanted Materials.
2. Histology:
 - a. Please process any pathology or blood serum specimens according to your usual practice. (For example, preserve in formalin, place into a paraffin block, and cut slides).
3. Medical Devices:
 - a. With regard to retrieved or explanted medical devices, sterilization/decontamination may be conducted via use of ethylene oxide, Cidex®, or a minimum of 1-hour soak in 10% neutral buffered formalin followed by a rinse with distilled water. If these methods are not available to you, please contact counsel at the contact information listed below. Thereafter, please place the medical device in an appropriate leak-proof container. **EXCEPT AS NOTED ABOVE, PLEASE DO NOT PLACE THE MEDICAL DEVICE IN FORMALIN OR ANY OTHER FIXATIVE AND DO NOT AUTOCLAVE COMPONENTS.**

Instructions for Shipping:

Please complete the enclosed Chain of Custody form describing the Material(s). Please forward it along with all of the Material(s) to:

[INSERT RECIPIENT]

Instruction for Reimbursement for Costs Incurred

For reimbursement of costs incurred in the collection, preservation, and shipping of the Material(s), please submit an itemized invoice to:

[Counsel for Plaintiff's contact information]

In order to facilitate this request, enclosed please find a HIPAA-compliant authorization for the release of the Material(s), signed by [Plaintiff's name].

Should you have any questions or concerns regarding this matter, please feel free to contact me.

If you are not the appropriate recipient of this request, please notify and forward a copy of this letter to the appropriate person or entity responsible for ensuring compliance with the terms of this request at your earliest convenience. Thank you very much for your assistance.

Very truly yours,

[Counsel for Plaintiff]

Enclosures

cc: *Zimmer Defendants' Counsel*

ATTACHMENT B

CHAIN OF CUSTODY FORM

Case/Cause No.:

ENTRY NO. 1

RELEASING Party Information:

Person/Facility Name: _____

Person/Facility Address: _____

Description of Materials Being Released:

A. Name of patient/plaintiff from whom Materials were explanted: _____

B. Date of birth of patient: _____

C. General description of Material (including product/catalogue ID number if known and number of components and/or fragments separated from components):

Full Name of Person Releasing Material: _____

Title: _____

Date Released: _____ Time Released: _____

Released to: _____

Manner in which Released (FedEx, etc.): _____

Tracking or Shipping No.: _____

Signature: _____

RECEIVING Party Information:

Person/Facility Name: _____

Person/Facility Address: _____

Description of Materials Being Received:

- A. Name of patient/plaintiff from whom Materials were explanted: _____
- B. Date of birth of patient: _____
- C. General description of Material (including product/catalogue ID number if known and number of components and/or fragments separated from components):

Full Name of Person Receiving Material: _____

Title: _____

Date Received: _____ Time Received: _____

Material Received from: _____

Manner in which Received (FedEx, etc.): _____

Tracking or Shipping No.: _____

Signature: _____

ENTRY NO. 2

RELEASING Party Information:

Person/Facility Name: _____

Person/Facility Address: _____

Description of Materials Being Released:

- A. Name of patient/plaintiff from whom Materials were explanted: _____
- B. Date of birth of patient: _____
- C. General description of Material (including product/catalogue ID number if known and number of components and/or fragments separated from components):

Full Name of Person Releasing Material: _____

Title: _____

Date Released: _____ Time Released: _____

Released to: _____

Manner in which Released (FedEx, etc.): _____

Tracking or Shipping No.: _____

Signature: _____

RECEIVING Party Information:

Person/Facility Name: _____

Person/Facility Address: _____

Description of Materials Being Received:

- A. Name of patient/plaintiff from whom Materials were explanted: _____
- B. Date of birth of patient: _____
- C. General description of Material (including product/catalogue ID number if known and number of components and/or fragments separated from components):

Full Name of Person Receiving Material: _____

Title: _____

Date Received: _____ Time Received: _____

Material Received from: _____

Manner in which Received (FedEx, etc.): _____

Tracking or Shipping No.: _____

Signature: _____

ATTACHMENT C

**VERY IMPORTANT—REQUEST FOR PRESERVATION OF PATHOLOGY
MATERIALS AND/OR MEDICAL DEVICES FROM PREVIOUS PROCEDURE**

[Date]

Attn: Departments of Surgery and Pathology
[Address of Retrieval/Explant Facility]

Re: [Case Caption]

Dear Departments of Surgery and Pathology:

I represent the Plaintiff, [Plaintiff's name], and the attorneys copied below represent the Zimmer Defendants in the above-referenced lawsuit. There is no litigation pending against your facility or the treating physician in this matter. I write to request the preservation of blood serum, pathology materials, and/or medical devices ("Materials") from [Plaintiff's name]'s previous procedure, which was performed by Dr. [Retrieval/Explant Physician] on [date].

It is very important that any pathology and/or medical devices obtained from this previous procedure be preserved for future analysis by the parties' respective experts. To the extent you have not already done so, the parties request that you preserve the Material(s) obtained as follows:

Instructions for Immediate Preservation of the Material(s):

1. Please preserve **all** retrieved or explanted Materials.
2. Histology:
 - a. Please process any blood serum or pathology specimens according to your usual practice. (For example, preserve in formalin, place into a paraffin block, and cut slides).
3. Medical Devices:
 - a. With regard to retrieved or explanted medical devices, sterilization/decontamination may be conducted via use of ethylene oxide, Cidex®, or a minimum of 1-hour soak in 10% neutral buffered formalin followed by a rinse with distilled water. If these methods are not available to you, please contact counsel at the contact information listed below. Thereafter, please place the medical device in an appropriate leak-proof container. EXCEPT AS NOTED ABOVE, PLEASE DO NOT PLACE THE MEDICAL DEVICE IN FORMALIN OR ANY OTHER FIXATIVE AND DO NOT AUTOCLAVE COMPONENTS.

4. If the Materials have already been preserved in a different manner, please keep the Materials in the manner that they are currently preserved.

Instructions for Shipping:

Please complete the enclosed Chain of Custody form describing the Material(s). Please forward it along with all of the Material(s) to:

[INSERT RECIPIENT]

Instruction for Reimbursement for Costs Incurred

For reimbursement of costs incurred in the collection, preservation, and shipping of the Material(s), please submit an itemized invoice to:

[Counsel for Plaintiff's contact information]

In order to facilitate this request, enclosed please find a HIPAA-compliant authorization for the release of the Material(s), signed by [Plaintiff's name].

Should you have any questions or concerns regarding this matter, please feel free to contact me.

If you are not the appropriate recipient of this request, please notify and forward a copy of this letter to the appropriate person or entity responsible for ensuring compliance with the terms of this request at your earliest convenience. Thank you very much for your assistance.

Very truly yours,

[Counsel for Plaintiff]

Enclosures

cc: *Zimmer Defendants' Counsel*